

IFW  
Docket No.: 2870-0335PUS1  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Junji NISHIGAKI

Application No.: 10/579,912

Confirmation No.: @@@

Filed: May 19, 2006

Art Unit: N/A

For: CONTRAST MEDIUM COMPRISING  
LIPOSOMES CONTAINING HYDROPHOBIC  
CHELATE COMPOUND

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

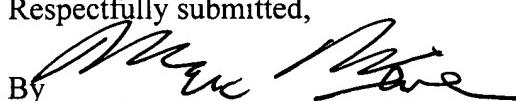
Sir:

Attached is a copy of the English version of International Preliminary Report on Patentability of Chapter I, i.e., International Search Opinion received from WIPO as the International Bureau of the PCT. Please make this of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

Dated: OCT 3 2006

Respectfully submitted,

By 

Marc S. Weiner

Registration No.: 32,181  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

## PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION CONCERNING  
 TRANSMITTAL OF COPY OF INTERNATIONAL  
 PRELIMINARY REPORT ON PATENTABILITY  
 (CHAPTER I OF THE PATENT COOPERATION  
 TREATY)  
 (PCT Rule 44bis.1(c))

To:

SIKs & Co.  
 8th Floor, Kyobashi-Nisshoku Bldg., 8-7, Kyobashi  
 1-chome, Chuo-ku, Tokyo  
 1040031  
 JAPON

Date of mailing (*day/month/year*)  
 01 June 2006 (01.06.2006)

Applicant's or agent's file reference  
 A41712M

**IMPORTANT NOTICE**

International application No.  
 PCT/JP2004/017649

International filing date (*day/month/year*)  
 19 November 2004 (19.11.2004)

Priority date (*day/month/year*)  
 21 November 2003 (21.11.2003)

Applicant

FUJI PHOTO FILM CO., LTD. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO  
 34, chemin des Colombettes  
 1211 Geneva 20, Switzerland

Authorized officer

**Yoshiko Kuwahara**

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 90 90

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference <b>A41712M</b>	<b>FOR FURTHER ACTION</b>	
	See item 4 below	
International application No. <b>PCT/JP2004/017649</b>	International filing date ( <i>day/month/year</i> ) <b>19 November 2004 (19.11.2004)</b>	Priority date ( <i>day/month/year</i> ) <b>21 November 2003 (21.11.2003)</b>
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant <b>FUJI PHOTO FILM CO., LTD.</b>		

<ol style="list-style-type: none"> <li>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</li>   <li>2. This REPORT consists of a total of 5 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</li>   <li>3. This report contains indications relating to the following items:           <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/></td> <td><b>Box No. I</b></td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. II</b></td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. III</b></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. IV</b></td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><b>Box No. V</b></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. VI</b></td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. VII</b></td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. VIII</b></td> <td>Certain observations on the international application</td> </tr> </table> </li>   <li>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</li> </ol>	<input checked="" type="checkbox"/>	<b>Box No. I</b>	Basis of the report	<input type="checkbox"/>	<b>Box No. II</b>	Priority	<input type="checkbox"/>	<b>Box No. III</b>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	<b>Box No. IV</b>	Lack of unity of invention	<input checked="" type="checkbox"/>	<b>Box No. V</b>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	<b>Box No. VI</b>	Certain documents cited	<input type="checkbox"/>	<b>Box No. VII</b>	Certain defects in the international application	<input type="checkbox"/>	<b>Box No. VIII</b>	Certain observations on the international application
<input checked="" type="checkbox"/>	<b>Box No. I</b>	Basis of the report																						
<input type="checkbox"/>	<b>Box No. II</b>	Priority																						
<input type="checkbox"/>	<b>Box No. III</b>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																						
<input type="checkbox"/>	<b>Box No. IV</b>	Lack of unity of invention																						
<input checked="" type="checkbox"/>	<b>Box No. V</b>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																						
<input type="checkbox"/>	<b>Box No. VI</b>	Certain documents cited																						
<input type="checkbox"/>	<b>Box No. VII</b>	Certain defects in the international application																						
<input type="checkbox"/>	<b>Box No. VIII</b>	Certain observations on the international application																						

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p>	<p>Date of issuance of this report <b>22 May 2006 (22.05.2006)</b></p> <p>Authorized officer <b>Yoshiko Kuwahara</b></p> <p>Telephone No. +41 22 338 90 90</p>
--	--

**PATENT COOPERATION TREATY**

From the  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 17 MAR. 2005
PCT
WIPO
PCT

To:

**SIKs & Co.**  
**8th Floor, Kyobashi-Nisshouku**  
**Bldg.,**  
**8-7, Kyobashi 1-chome,**  
**Chuo-ku, Tokyo**  
**1040031 JAPAN**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year)

**15. 3. 2005**

Applicant's or agent's file reference

**A41712M**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.  
**PCT/JP2004/017649**

International filing date (day/month/year)

**19.11.2004**

Priority date (day/month/year)

**21.11.2003**

International Patent Classification (IPC) or both national classification and IPC  
Int.Cl' **A61K9/127, A61K47/24, A61K49/18**

Applicant

**FUJI PHOTO FILM CO., LTD.**

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Date of completion of this opinion

**22.02.2005**

Name and mailing address of the ISA/JP

**Japan Patent Office**

3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan

Authorized officer

**4C 8828**

**MOTOHIRO OKUBO**

Telephone No. +81-3-3581-1101 Ext. 3452

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
**PCT/JP2004/017649**

**Box No. I Basis of the opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- a sequence listing  
 table(s) related to the sequence listing

b. format of material

- in written format  
 in computer readable form

c. time of filing/furnishing

- contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.

3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
**PCT/JP2004/ 017649**

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	<u>3 , 4 , 6 - 8</u>	YES
	Claims	<u>1 , 2 , 5</u>	NO
Inventive step (IS)	Claims	<u>                  </u>	YES
	Claims	<u>1 - 8</u>	NO
Industrial applicability (IA)	Claims	<u>1 - 8</u>	YES
	Claims	<u>                  </u>	NO

**2. Citations and explanations**

**D1 : WO 97/46262 A2 (PHARMACYCLICIS INC) 1997.12.11**

see the whole document, especially

claims ;

line 24,page 1 to line 27, page 2 ;

line 16-29, page 8 ;

line 2-29, page 14 ;

page 49 ;

example 5-7

& AU 9732264 B & EP 954336 A2 & JP 2000-512279 A & US 2002/6378 A

**D2 : WO 96/11023 A1 (NYCOMED IMAGING AS) 1996.04.18**

see the whole document, especially

claims ;

line 3-14, page 18 ;

examples

& AU 9536136 B & EP 785804 A1 & JP 10-507172 A & US 6045821 A

**D3 : SCHWENDENER RA 'Liposomes as carriers for paramagnetic gadolinium chelates as organ specific contrast agents for magnetic resonance imaging (MRI).' Journal of Liposome Research, (1994) vol.4 no.2 p.837-855**

see the whole document

**D4 : WO 03/18530 A1 (FUJI PHOTO FILM CO LTD) 2003.03.06**

see the whole document, especially

claims ;

line 28-34, page 14 ;

line 41, page 15 to line 8, page 16 ;

example 1

& EP 1426353 A1 & US 2005/2864 A

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
**PCT/JP2004/017649**

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box No.V**

**(1) < claims 1,2 & 5 >**

The subject matter of claims 1,2 & 5 appears neither to be novel nor to involve an inventive step with respect to any of D1-D3. D1-D3 disclose the MRI contrast medium which comprises a liposome containing, as a membrane component, a chelate compound with a hydrophobic moiety.

**(2) < claims 3,4 & 6-8 >**

None of the subject matter of claims 3,4 & 6-8 involves an inventive step with respect to D1-D4.

None of D1-D3 concretely describes any liposomes which contain phosphatidylcholine (PC) and phosphatidylserine (PS), as membrane components, with molar ratio 3:1-1:2. However, D4 discloses that liposomes useful for MRI contrast media are likely to accumulate on foam macrophages detected frequently in the lesions due to atherosclerosis, tumor, inflammation, infection and the like when the liposomes contain PC and PS with the above-described ratio as membrane components. Taking that into consideration, a person skilled in the art would easily employ PC and PS with the above-described ratio as membrane components of liposomes disclosed in D1-D3.